

(12) UK Patent Application (19) GB (11) 2 139 902 A

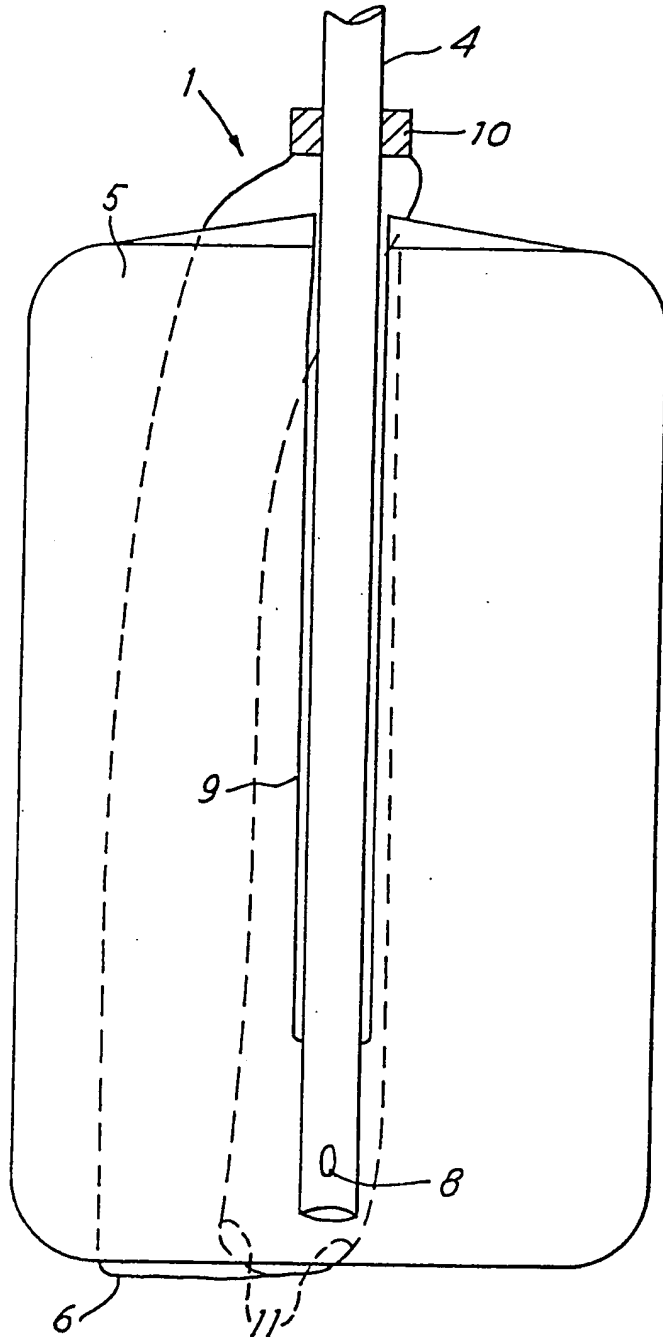
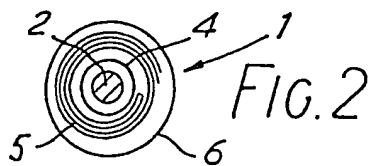
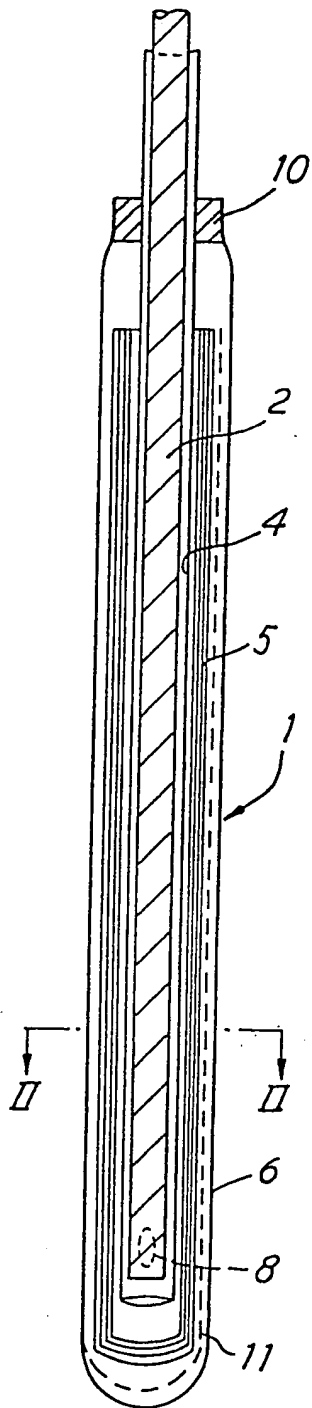
(43) Application published 21 Nov 1984

(21) Application No 8412554	(51) INT CL ³ A61F 5/00
(22) Date of filing 17 May 1984	(52) Domestic classification A5R EY
(30) Priority data	(56) Documents cited
(31) 8313639 (32) 17 May 1983 (33) GB	GB A 2090747 EP A 0086862 GB 1530565 WO 8302888 EP A 0103481
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(54) Balloon introducer apparatus

(57) Apparatus for inserting and inflating a balloon in a patient's stomach in the treatment of obesity comprises means for introducing the balloon inflating it after introduction and removing the introducer. Suitably the balloon is carried within a wrapper at the end of introducer means in the form of a rod surrounded by a tube. After positioning of the balloon, the rod is withdrawn and the balloon inflated, bursting the wrapper, by gas or by gas-forming chemicals supplied through the tube and a non-return valve, after which the tube is withdrawn with the split wrapper.

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SPECIFICATION

Balloon introducer apparatus

- 5 The invention relates to apparatus for inserting and inflating a balloon in a patient's stomach in the treatment of obesity.

In accordance with the invention there is provided balloon introducer apparatus comprising a balloon
10 carried at the distal end of elongate introducer means arranged to permit introduction of the balloon into the stomach in a deflated condition and balloon inflation in the required location, the balloon being associated with the introducer means so as to
15 permit withdrawal thereof from the inflated balloon without substantial loss of inflation.

The apparatus can thus comprise a balloon having a non-return valve through which the balloon can be inflated, an outer wrapping for the balloon in a
20 deflated condition from which the balloon can escape on inflation, and elongate introducer means by which the balloon within the wrapping can be placed at a desired location in the stomach and then inflated through the non-return valve, the wrapper
25 being secured to the introducer means for withdrawal therewith after inflation of the balloon at the desired location.

The elongate introducer means must provide a degree of mechanical strength as well as a conduit
30 for supplying fluid to the balloon interior to effect inflation, and can comprise a rod of appropriate rigidity to act as a pusher during introduction of the balloon and a tube within which the rod is received and by which air or other fluid can be supplied to the
35 balloon to effect inflation. The rod can be withdrawn independently of the tube after placement of the balloon and prior to inflation, the wrapping being secured to the tube. The deflated balloon can be flattened so that it can be coiled round the tube or
40 folded so as to occupy a limited volume within the wrapper, with the tube extending through the non-return valve into communication with the balloon interior.

For a better understanding of the invention reference may be made to the following illustrative description and the accompanying drawings, in which:

Figure 1 is a sectional side view of the distal end of a balloon introducer apparatus embodying the invention, shown in its initial condition;

Figure 2 is a cross-sectional view of the apparatus on the line II-II of *Figure 1*; and

Figure 3 is a sectional side view of the apparatus of *Figure 1* but with the balloon in the inflated condition.

The illustrated balloon-introducer apparatus 1 comprises four components shown in *Figures 1* and 2 assembled together ready for use. These components comprise a rod 2 received within a tube 4
60 having at its distal end a balloon 5 in a deflated condition wrapped around it. Finally, an outer casing or wrapper 6 encloses the balloon and is sealed to the exterior of the tube 4.

The rod 2 is of any suitable material and length for
65 giving an appropriate degree of structural rigidity to

the apparatus for enabling the balloon 5 within the wrapper 6 to be inserted into the patient's stomach. The tube 4 within which the rod 2 extends is suitably of flexible plastics material and has at its proximal end (not shown) means whereby its interior can be put in communication with a source of liquid or air or other gas under pressure. Towards its open distal end, the tube 4 is provided with one or more apertures 8 for communication with the interior of the balloon 5 through a one-way or non-return valve 9 incorporated into the balloon structure.

The balloon 5 is made of any suitable material, for example plastics sheet material, capable of retaining air or liquid for an appropriate length of time and can be inflated to a general cylindrical shape of suitable dimensions, for example, a length of 14 cm. and a diameter of 9 cm. The non-return valve 9 is preferably of the lay-flat variety and is formed so as to extend either along the cylindrical side wall of the
85 balloon from its proximal end to a position short of the distal end, or is free-lying in an exactly similar manner. During assembly of the balloon 5 with the rod 2 and the tube 4, the distal ends of the rod and tube are inserted through the valve 9 so as to extend beyond it into the balloon interior. The deflated
90 balloon 5 is flattened or folded so as to extend on either side of the tube 4 and is then furled tightly about the tube into the compact cylindrical configuration shown in *Figures 1* and 2.

To facilitate introduction of the balloon 5 and to hold it in its coiled condition, the balloon is received within the outer wrapper 6 which has the form of a tube with one end closed. The balloon on the rod 2 and tube 4 is inserted through the open end of the wrapper 6, and this end is then sealingly secured to the tube as by a heat seal 10. The wrapper 6 is provided with at least one line 11 of perforations extending longitudinally and across the closed end, or is otherwise weakened along such a line or lines.

In use, the patient swallows the balloon 5 coiled within the wrapper 6 and the balloon is located where desired in the stomach by use of the rod 2 as a pusher. The rod 2 can then be withdrawn and air or other fluid under pressure is connected to the
110 proximal end of the tube 4. The fluid leaves the end of the tube 4 to enter the balloon 5 inwardly of the non-return valve 9 and causes the balloon to distend. The balloon expansion quickly splits the wrapper 6 along the perforated line 11 so that the balloon escapes and is free to expand to its predetermined maximum size as shown in *Figure 3*. The balloon 5 is thus lodged as required within the stomach and the tube 4 can then be withdrawn, carrying the split wrapper 6 along with it.

Inflation in situ of the balloon can instead be effected by means of a chemical reaction which generates an appropriate volume of gas. The reagents employed are conveniently both liquids, introduced successively through the tube 4 after the
125 balloon has been positioned in the stomach. Thus a first liquid containing a carbonate can be introduced, followed by a weak acid. On reaching the balloon, the acid will react with the carbonate inside it to liberate carbon dioxide to effect inflation.

One or more of the components of the apparatus

can be radio-opaque, at least in part, so that its position can be checked by X-ray examination. Additionally or instead, where inflation is effected by chemical means, at least one of the reagents, for example, the carbonate mentioned above, can be chosen so as to be radio-opaque.

The invention can of course be embodied in other forms of apparatus than as specifically described.

13. An apparatus substantially as herein described with reference to the accompanying drawing.

Printed in the UK for HMSO, D8818935, 9/84, 7102.
Published by The Patent Office, 25 Southampton Buildings, London,
WC2A 1AY, from which copies may be obtained.

10 CLAIMS

1. An apparatus comprising an elongate introducer means, an inflatable balloon carried at the distal end of the introducer means, and means for inflating the balloon after introduction thereof to a desired site, the introducer means being separable from the balloon after inflation thereof.

2. An apparatus as claimed in claim 1 wherein the means for inflating the balloon comprises passage means extending along the introducer means to permit supply of fluid or of fluid forming materials to the balloon interior from the region of the proximal end of the introducer means.

3. An apparatus as claimed in claim 2 having a non-return valve for communication of fluid or fluid forming materials from the passage means into the balloon interior.

4. An apparatus as claimed in claim 2 or 3 wherein at least one of the fluid forming materials is radio-opaque.

5. An apparatus comprising an elongate introducer means for introducing an inflatable balloon into the human stomach and for effecting inflation of the balloon being associated with the introducer means in a manner permitting withdrawal of the introducer means after inflation of the balloon with substantial loss of the inflation.

6. An apparatus as claimed in claim 5 wherein the introducer means comprises a tube and a rod received therein, the balloon being inflatable by fluid supplied through one or more apertures at the distal end of the tube and a non-return valve or by gas generated by reactive chemicals so supplied.

7. An apparatus as claimed in claim 6 wherein the balloon is inflatable to an approximately cylindrical shape and has the non-return valve formed along the cylindrical wall thereof.

8. An apparatus as claimed in claim 6 or 7 wherein at least one of the reactive chemicals is radio-opaque.

9. An apparatus as claimed in any preceding claim wherein the deflated balloon is coiled around the tube.

10. An apparatus as claimed in any preceding claim having a wrapper secured to the introducer means, the wrapper surrounding the deflated balloon and being rupturable on inflation thereof.

11. An apparatus as claimed in claim 10 wherein the wrapper is formed with one or more perforated lines or lines of weakening to assist the rupturing thereof.

12. An apparatus as claimed in any preceding claim wherein either or both of the introducer means and the balloon is at least partially radio-opaque or carries radio-opaque markings.

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